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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,978	01/21/2004	Howard Cohen	479-P-007B	4044

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HOWARD C. MISKIN
C/O STOLL, MISKIN, & BADIE
THE EMPIRE STATE BUILDING
350 FIFTH AVENUE SUITE 4710
NEW YORK, NY 10118

EXAMINER

SNOW, BRUCE EDWARD

ART UNIT PAPER NUMBER

3738

DATE MAILED: 01/19/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/761,978

Applicant(s)

COHEN ET AL. *CM*

Examiner

Bruce E Snow

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2004 and 27 December 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-42 is/are pending in the application.
- 4a) Of the above claim(s) 8-11, 16-23, 25-37 and 42 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-7, 12-15, 24 and 38-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1) ☐ Certified copies of the priority documents have been received.
 - 2) ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3) ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION***Election/Restrictions***

Applicant's election of Invention I (group I), Species 14 (figure 16), and anti-microbial drug eluting factors" in the replies filed on 8/11/04 and 12/27/04 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

Claims 8-11, 16-23, 25-37 and 42 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention/species.

Regarding claim 21, applicant fails to teach the elected embodiment which allows the movement of adjacent vertebrae comprising two or pair of plates.

Drawings

The drawings are objected to under 37 CFR 1.83(a) because they fail to show at least claims 13-15, 38, 39 claiming a supplemental support as described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and

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where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency.

Additional replacement sheets may be necessary to show the renumbering of the remaining figures. The replacement sheet(s) should be labeled "Replacement Sheet" in the page header (as per 37 CFR 1.84(c)) so as not to obstruct any portion of the drawing figures. If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

At least claims 13-15, 38, 39 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. One of ordinary skill the art cannot conceive applicant's claim of a supplemental support in combination with elected embodiment as claimed and make and/or use the device.

Additionally, claim 24 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The specification does not enable one of

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ordinary skill in the art to make and/or use a "substance with anti-microbial drug eluting factors". This is not found in the specification and unclear as what the substance is or does.

Claim Rejections - 35 USC § 112

Claim 24 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The current application is a divisional of 6,719,796 which does not support a "substance with anti-microbial drug eluting factors".

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 24, 40, 41 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 24, what is a "substance with anti-microbial drug eluting factors"?

Claim 40 is ambiguous. Both modular sets and means for connecting lack antecedent basis. Upon clarification, this claim might be withdrawn similar to claim 21 not generic to the elected species.

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Claim 41 is ambiguous.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 1-5, 12-13 are rejected under 35 U.S.C. 102(e) as being clearly anticipated by Cauthen (6,019,792).

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Cauthen teaches an artificial disc for placement between adjacent vertebrae comprising:

at least two plate members 20, 22, each plate member having a corresponding surface:

at least one means for temporarily stabilizing said plate members for a certain period of time to allow at least two of said plate members to osteo-integrate with adjacent vertebrae (see elements 82, 94, etc and at least 3:7 et seq. and 6:43 et seq.); and

at least one flexible supporting means (see element 90 in figure 5) interposed between said plate members and abutting said corresponding surfaces, said flexible support means flexibly supporting said plate members after said certain period of time.

Regarding claim 4, the plate members are made of titanium and therefore, ball element 42 is titanium which is interpreted as a portion of the flexible supporting means.

Regarding at least claim 12, "rigid collar surrounding", see 7:7 et seq. teaching filling a biodegradable polymer between the plate members which forms a collar.

Regarding at least claim 13, "supplemental support", see the bioabsorbable endcap 90.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 24 and 14-15, 38, 39 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cauthen (6,019,792) in view of Shinn et al (5,683,465).

Cauthen teaches the artificial disc as described above including using drugs for bone ingrowth (see 8:12 et seq.), however, is silent regarding a “substance with anti-microbial drug eluting factors”. Shinn et al teaches a similar artificial disc which uses drugs to promote healing including an antibiotic. It would have been obvious to one having ordinary skill in the art have used an antibiotic as taught by Shinn et al or any other drug known in the art of prosthetics to promote healing, lessen the chances of infection or simply improve implantation of the disc in bone.

Regarding claims 14-15 and 38-39, Cauthen teaches the artificial disc as described above including using “one or more stabilizing means for temporarily rigidly coupling the first [plate] and second [plate]. It would have been obvious to one having ordinary skill in the art to have utilized any known stabilizing means known in the art as deemed necessary by the surgeon. Additionally, lacking any criticality in the specification, the use of the specifically claimed supplemental support.

Claim 4, 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cauthen (6,019,792) in view of Gauchet et al (6,733,532).

Cauthen teaches the artificial disc as described above, however, fails to teach the flexible disc has opposed convex surfaces. Gauchet et al also teaches an artificial disc which can have a single convex surface like Cauthen (see figure 6 of Gauchet et al), or can have opposed convex surfaces. It would have been to one having ordinary

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skill in the art to have utilized the opposed convex surfaces configuration taught by Gauchet et al with the device of Cauthen as a know alternative/equivalent configuration.

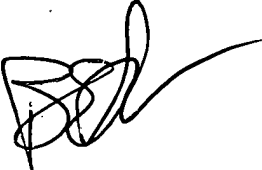
Regarding claim 4, not Gauchet et al further teaches bellows 22 made of titanium as an additionally flexible supporting means and would have been obvious to one having ordinary skill in the art to have used on the disc of Cauthen for additionally cushioning or limit of flexibility.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bruce E Snow whose telephone number is (571) 272-4759. The examiner can normally be reached on Mon-Thurs.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4754. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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BRUCE SNOW
PRIMARY EXAMINER